

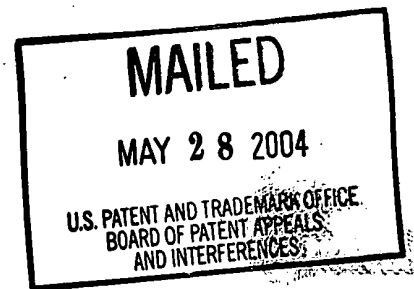
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte Raymond J. Bergeron

Appeal No. 2004-1008
Application No. 10/091,591

ON BRIEF¹



Before ADAMS, MILLS, and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

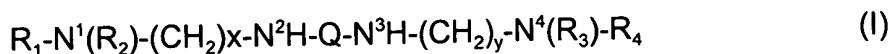
DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-7, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. An anti-diarrheal or gastrointestinal anti-spasmodic pharmaceutical composition comprising [A] an effective amount of a compound having the formula:

¹ Appellant waived his request for oral hearing. Paper No. 18, received April 29, 2004. Accordingly, we considered this appeal on Brief.



wherein: R_1 , R_2 , R_3 , R_4 are the same or different and are H, alkyl, cycloalkyl or aralkyl having from 1 to 12 carbon atoms, or a heterocyclic group having from 3 to 10 atoms wherein the hetero atom is said N^1 or N^4 ; Q is a cycloalkyl group having from 3 to 10 carbon atoms; x is an integer from 3 to 6, inclusive; and y is an integer from 3 to 6, inclusive; or (II) a salt thereof with a pharmaceutically acceptable acid; and [B] a pharmaceutically acceptable carrier therefor.

The examiner relies on the following reference:

Bergeron, Jr. (Bergeron)

5,962,533

Oct. 5, 1999

GROUND OF REJECTION

Claims 1-7 stand rejected under 35 U.S.C. § 102(b) as anticipated by Bergeron.

We affirm.

DISCUSSION

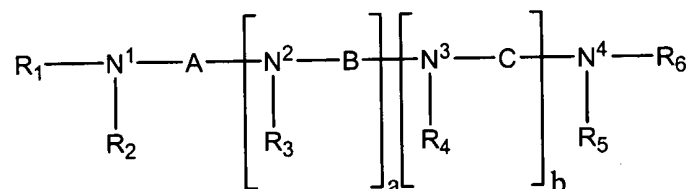
Given its brevity we reproduce the examiner's statement of the rejection in full:

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by 5,962,533 [Bergeron]. '533 discloses compositions (column 3, lines 59-60) comprising the instant compound (column 4, Table 1, compounds 33 and 34) and that they are used to treat diarrhea. Table 1, compounds 33-34 disclose a compound in which Q is a cyclohexyl group connected as the trans isomer, R_1 [sic] and R_4 [sic] are CH_2CH_3 [sic], R_2 [sic] and R_3 [sic] are H and x and y are 4. This corresponds to the compound of the composition of claims 1, 2, 3 and 7 in which R_1 [sic] and R_4 [sic] are alkyl, R_2 [sic] and R_3 [sic] are H, Q is a cyclohexyl group connected as the trans isomer and x and y are 4.

It is noted that appellant has not argued the specific limitations of dependent claim 4-6. Furthermore, he recites on page 3 of the Brief that "The appealed claims stand or fall together."

As we understand the examiner's statement, appellant's claims are anticipated by compounds 33 and 34 as set forth in Table 1 of Bergeron. The examiner is correct in that Bergeron discloses (column 3, lines 59-62), an "object of the invention [is] to provide novel pharmaceutical compositions methods of treating human and non-human animals with the novel polyamine derivatives." However, contrary to the examiner's assertion, according to Bergeron (column 3, line 65 through column 4, line 37, emphasis added):

The above and other objects are realized by the present invention, one embodiment of which comprises polyamines having the formula:



... wherein at least one of the bridging groups A, B and C contains at least one -CH(OH)- group which is not alpha- to either of the nitrogen atoms.

As appellant points out (Brief, page 5, emphasis original), "the only polyamines disclosed by the patent (other than those disclosed in col. 17, lines 27-59²) to be effective anti-diarrheals are those ... which contain at least one CH(OH) group in at least one of the bridging groups." In contrast, in appellant's claimed invention none of the bridging groups contain CH(OH) groups. Brief, page 5. In response, the examiner finds (Answer, page 4), since "claim 1 recites

² The examiner presents no evidence on this record that the other anti-diarrheals DEHSPM, (HO)₂DEHSPM, DENSPM, DPNSPM and HSPM as set forth in col. 17, lines 27-59 of Bergeron, fall within the scope of the formula set forth in appellant's claims. In this regard, we note that Table 1 of Bergeron, sets forth the structure of DENSPM, No. 11 and DEHSPM, No. 20 of Bergeron. In addition, Table 3 of Bergeron sets forth the structure of DEHSPM, and (HO)₂DEHSPM.

a '...composition comprising... an efective [sic] amount of a compound...' [t]he instant comprising language is open-ended and does not exclude the CH(OH) group of ... [Bergeron]." In this regard, we agree with appellant (Reply Brief, page 2),

the so-called "comprising language" does not modify the definition of the active anti-diarrheal, i.e., the polyamine. The language of the claim defining the polyamine is the structural formula (I) of claim 1 which, when read in conjunction with the "wherein" clause appearing immediately thereafter, ... excludes the CH(OH) group containing polyamines disclosed by ... [Bergeron] to be useful for the treatment of diarrhea.

Stated differently, the word "comprising" modifies the composition not the compound of formula I. Thus the composition may comprise the compound of formula I and other ingredients, but the compound itself has must be consistent with the requirements of formula I.

Nevertheless, appellant does not dispute that compounds 33 and 34, as set forth in Table 1 of Bergeron, "are embraced by the structural formulae of the rejected claims." Brief, page 5. Appellant, however, asserts (Brief, bridging paragraph, pages 5-6, emphasis removed), "there is no disclosure in the reference that compounds 33 and 34 are anti-diarrheals. There is no disclosure in the reference of a pharmaceutical composition suitable for the treatment of diarrhea that contains either compound 33 or 34." According to appellant (Brief, page 6),

Table 1 of the patent sets forth the calculated and actual K_i values for a wide variety of polyamines. The table was compiled by patentee as a first step in trying to predict which polyamines would be effective anti-diarrheals. See col. 6, lines 25-60. Table 1 ... includes 34 compounds and, as stated above, merely delineates the K_i values for the listed polyamines.

In this regard, we note that the examiner fails to identify any portion of Bergeron that describes a composition-comprising compound 33 or 34. We do, however, recognize the examiner's argument (Answer, page 4), "the fact that compounds 33 and 34 are not disclosed as having anti-diarrheal properties does not remove them as references. It is well-established that intended use does not impart patentability in a composition claim." See In re Zierden 411 F.2d 1325, 1329, 162 USPQ 102, 104 (CCPA 1969):

A mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable. As we said in In re Lemin, 51 CCPA 942, 326 F.2d 437, 140 USPQ 273, 276 (1964),

Appellants are clearly correct in demanding that the subject matter as a whole must be considered under 35 U.S.C. 103. But in applying the statutory test, the differences over the prior art must be more substantial than a statement of the intended use of an old composition. ... It seems to us that the composition ... would be exactly the same whether the user were told to cure pneumonia in animals with it ... or to promote plant growth with it (as here). The directions on the label will not change the composition....

See also, In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir.

1990) ("[t]he discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, cannot impart patentability to claims to the known composition"). Accordingly, claim 1³ simply requires a composition-comprising compound of formula I and a pharmaceutically acceptable carrier.

³ According to appellant (Brief, page 3), "[t]he appealed claims stand or fall together." Accordingly, we limit our discussion to representative independent claim 1. Claims 2-7 stand or fall together with claim 1. 37 CFR § 1.192(c)(7) (2002).

As set forth in Bergeron (column 19, lines 35-32), "[a]ll of the compounds [of Table 1] were screened for their 48 and 96 hour IC_{50} values in L1210 cell culture assays." At column 20, lines 45-50, Bergeron discloses that to determine IC_{50} values, the polyamine derivatives of Table 1 were diluted in sterile water and filtered through a 0.2 μ m filter. In our opinion sterile water is a pharmaceutically acceptable carrier. Thus, Bergeron discloses a composition comprising a compound of formula 1 (see Table 1, compounds 33 and 34) in a pharmaceutically acceptable carrier (sterile water).

The question remains, however, as to whether Bergeron teaches a composition comprising an amount of compound 33 or 34 that would meet the requirements of appellant's claimed invention? While appellant's specification does not explicitly define the phrase "an effective amount", appellant discloses (page 11, lines 12-15), "[p]harmaceutical compositions according to the invention can, for example, ... contain from approximately 0.05 g to approximately 10.0 g, and preferably from approximately 0.3 g to approximately 1.0 g, of active ingredient."⁴ While Bergeron does not teach the amount of the compound in the composition, it appears, absent evidence to the contrary that the composition of claim 1 is identical or substantially identical to the composition disclosed by Bergeron as useful in the determination of IC_{50} values. Appellant's burden under the circumstances presented herein was described in In re Best, 562 F.2d 1252,

⁴ See also, Specification, page 10, "a suitable dose of agent will lie in the range of about .0001 mg to about 500 mg per kilogram of mammal body weight being treated."

1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.... Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted].

We find no evidence on this record that the composition of Bergeron does not necessarily or inherently possess the characteristics of appellant's claimed composition. Accordingly, we affirm the rejection of claim 1 under 35 U.S.C. § 102(b) as anticipated by Bergeron. Claims 2-7 fall together with claim 1. However, since our basis for affirming the rejection differs from the examiner's, we designate the affirmance as a new ground of rejection under 37 CFR § 1.196(b) in order to provide appellant with a fair opportunity to respond. See In re Kronig, 539 F.2d 1300, 1302-03, 190 USPQ 425, 426-27 (CCPA 1976).

TIME PERIOD FOR RESPONSE

This opinion contains a new ground of rejection pursuant to 37 CFR § 1.196(b). 37 CFR § 1.196(b) provides that, "[a] new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the

following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

- (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner....
- (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record....

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED; 37 CFR § 1.196(b)



Donald E. Adams
Administrative Patent Judge



Demetra J. Mills
Administrative Patent Judge



Eric Grimes
Administrative Patent Judge

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